



**S/N 10/665,990**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Michael A. Apicella et al.      Art Unit : 1645  
Serial No. : 10/665,990      Examiner : Padmavathi Baskar  
Filed : September 19, 2003      Docket : 17023.031US1 / 01025  
Title : VACCINE AND COMPOSITIONS FOR THE PREVENTION AND  
TREATMENT OF NEISSERIAL INFECTIONS

**DECLARATION UNDER 37 CFR § 1.132**

1. I, Michael A. Apicella, am one of the co-inventor of the above-identified application.
2. We performed studies where various strains of *N. gonorrhea* have been prevented from associating with cultured primary cervical cells in the presence of Ab 1307. Below is a table showing the data generated studying three other clinical gonococci isolates/strains used to challenge pex cells. One strain was a cervical isolate ("cervical") (strain LT38097), one was from a patient with pelvic inflammatory disease ("PID") (strain PID6), and one strain was from a patient with disseminated gonococcal infection ("DGI") (SK92-679). The association/invasion assays were performed with or without anti-PLD Ab 1307 (1:20 dil<sup>n</sup>).

	Assay 1	Assay 2	Assay 3		Mean	Variance	P*
<i>Association PEX</i>							
DGI w/o Ab	30.92	26.89	31.56		29.79	2.07	0.05
DGI + 1307	7.14	6.40	6.22		6.59	0.40	
Cervical w/o Ab	30.61	27.36	31.79		29.92	1.87	0.05
Cervical + 1307	8.40	7.40	8.41		8.07	0.47	
PID w/o Ab	25.55	34.72	31.71		30.66	3.82	0.05
PID + 1307	12.04	12.88	14.91		13.28	1.20	
<i>Invasion PEX</i>							
DGI w/o Ab	0.77	0.88	0.95		0.87	0.07	0.05
DGI + 1307	0.39	0.40	0.40		0.40	0.005	
Cervical w/o Ab	2.32	2.47	2.41		2.40	0.06	0.05
Cervical + 1307	0.24	0.24	0.31		0.26	0.03	
PID w/o Ab	2.08	1.90	2.24		2.07	0.14	0.05
PID + 1307	0.58	0.95	0.66		0.73	0.16	

\* *P*-values were determined using a Kruskal-Wallis k-sample analysis of variance calculated for the association or invasion of gonococci in the presence of, compared to the absence of, anti-NgPLD immune sera 1307 for each gonococcus strain.

As can be seen from the data, presence of Ab 1307 effectively inhibited the ability of the various gonococcal strains from invading the cultured primary cervical cells.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

9/25/06

By:

  
Michael A. Apicella